UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

07 CV 3758

SUNSET CLIFFS THERAPEUTICS, INC.,

Plaintiff,

v.

OVAMED GmbH,

Defendant,

No. 07 Civ. _____

JUDGE RAKOFF

COMPLAINT

Sunset Cliffs Therapeutics, Inc. ("Sunset Cliffs"), by its attorneys, Covington & Burling LLP, for its Complaint against Ovamed GmbH ("Ovamed"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for a declaratory judgment as to Sunset Cliffs' rights and obligations under an Exclusive Sublicense Agreement entered into by defendant Ovamed and Sunset Cliffs' predecessor-in-interest, Collingwood Pharmaceuticals, Inc. ("Collingwood").

2. Collingwood and Sunset Cliffs are affiliates of Paramount Biosciences LLC ("Paramount"), a drug development and merchant banking firm that specializes in the in-licensing and clinical development of promising biotechnologies.

3. In 2005, Paramount created Collingwood to sublicense from Ovamed certain patent rights to develop and commercialize the ova of a parasite, *Tricuris suis* ova ("TSO"), as a treatment for various autoimmune diseases.

4. The agreement between the parties provided that Collingwood alone would finance and oversee the clinical development of TSO, shepherd it through the regulatory

approval process, and ultimately bring it to market. As exclusive sublicensee of the TSO rights, Collingwood was vested with sole discretion to control clinical and commercial development, so long as Collingwood's efforts were "commercially reasonable." The parties also negotiated an arrangement under which Ovamed would manufacture TSO and supply it to Collingwood at Collingwood's request.

5. Pursuant to the terms of the Sublicense Agreement, Collingwood recently assigned the Sublicense to Sunset Cliffs, its affiliate. As a result, Sunset Cliffs is now the exclusive sublicensee of the TSO rights.

6. In order to file an investigational new drug application ("IND") with the FDA and proceed with clinical development, Sunset Cliffs must perform a toxicology study required by the FDA. Months ago, Collingwood prepared a protocol for the toxicology study, and Sunset Cliffs is prepared to proceed with the study as soon as product is available that meets the FDA's standards for good manufacturing practice, or "GMP." To date, however, Ovamed has been unable to manufacture or supply TSO that meets the FDA's GMP standards. Ovamed's failure to supply GMP material has prevented Collingwood, and now Sunset Cliffs, from commencing the toxicology study that is a prerequisite to the filing and acceptance of an IND.

7. Although Sunset Cliffs' inability to commence the toxicology study and file an IND is caused by Ovamed's own ongoing manufacturing failure, Ovamed now asserts that the failure to file an IND application somehow constitutes a breach of the Sublicense Agreement. Ovamed demands that the IND be filed by a date certain, irrespective of the parties' agreement, the lack of GMP product, or the availability of new toxicological data. Ovamed has threatened to terminate the agreement if its demands are not met.

8. The motive behind Ovamed's insistence that the IND must be filed immediately is transparent — to accelerate a $1.5 million "milestone payment" to which Ovamed is entitled upon acceptance of the IND by the FDA. Indeed, before resorting to its claim of breach, Ovamed explicitly demanded that the binding terms of the Sublicense Agreement be renegotiated to de-link such payments from achievement of developmental milestones, and instead tie them to fixed deadlines.

9. The core of the parties' bargain, however, is their agreement that, while Ovamed would be entitled to milestone payments upon the achievement of certain steps in the regulatory approval process, Collingwood would have the sole discretion to determine in good faith when and how to achieve those milestones — including, at the most basic level, to determine what studies to conduct and how to conduct them in order to maximize the chances of FDA approval. Ovamed now seeks to invert that bargain by arrogating to itself the authority to determine what studies should be performed, and in what manner, before the IND is filed — *i.e.*, to dictate how Collingwood, and now Sunset Cliffs, should go about exploiting the assets that Collingwood paid to license — and, failing that, to exit the bargain by declaring a breach and trying to sublicense the TSO rights anew on more favorable terms.

10. Ovamed's actions impair Sunset Cliffs' ability to exploit its sublicense, and impede Sunset Cliffs from reliably formulating and executing a development plan for TSO so long as there is any practical uncertainty regarding the relative authority of Sunset Cliffs and Ovamed over that plan.

11. By this action, Sunset Cliffs seeks a declaration that: (i) Sunset Cliffs and its predecessor-in-interest, Collingwood, have not breached the Sublicense Agreement, (ii) Sunset Cliffs is not obligated under the Sublicense Agreement to achieve any milestone in the

development and commercialization of the sublicensed rights by a predetermined date certain, and (iii) under the Sublicense Agreement, Ovamed has no authority to decide the appropriate program and timeline for development and commercialization of the sublicensed rights.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(2) in that this is an action between a citizen of a state and a citizen of a foreign state, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

13. This Court has personal jurisdiction over Defendant Ovamed under CPLR § 302(a)(1) because the claim arises from Ovamed's transaction of business in New York and contracting to provide goods or services in New York.

14. Venue in this District is proper pursuant to 28 U.S.C. § 1391(d).

PARTIES

15. Plaintiff Sunset Cliffs is a corporation organized under the laws of Delaware with its principal place of business in California. Sunset Cliffs' predecessor-in-interest, Collingwood, is a Delaware corporation with its principal place of business in New York.

16. Upon information and belief, Defendant Ovamed is a limited liability company organized under the laws of the Federal Republic of Germany, with its principal place of business in Barsbüttel, Germany.

FACTS

The Origin of Ovamed's License and Collingwood's Sublicense

17. Paramount is a drug development firm and life sciences merchant bank that licenses promising biotechnology and pharmaceutical technology from inventors and corporations worldwide for clinical development and commercialization in the United States and other territories. Paramount establishes, funds, and operates start-up companies that oversee the clinical development of, and regulatory approval process for, the licensed technology, and ultimately bring the product to market. Over the past fifteen years, Paramount and its affiliates have been involved in the clinical development of many dozens of drug candidates (several of which have reached the market), and have over forty compounds in clinical development today.

18. This declaratory judgment action arises out of a project that Paramount undertook in 2005 to develop a biologic treatment for autoimmune diseases.

19. On information and belief, since approximately 1998, researchers at the University of Iowa have investigated the potential use of a parasite — the pig whipworm, *Tricuris suis* — in the treatment of Inflammatory Bowel Disease ("IBD"), including Crohn's disease and ulcerative colitis. The University of Iowa Research Foundation (the "University") holds patents in the United States and other jurisdictions relating to the use of *Tricuris suis* ova, or TSO, to treat these and other ailments.

20. Upon information and belief, Ovamed has facilities in Germany and Denmark to produce TSO. On September 25, 2003, the University granted Defendant Ovamed's predecessor, BioCure GmbH ("BioCure"), an exclusive license to certain uses of the TSO patent rights in Germany and other enumerated countries in Europe. At the same time, BioCure executed a Development, Manufacturing, and Commercialization Agreement with a German

company, Dr. Falk Pharma GmbH ("Falk"), pursuant to which BioCure would supply TSO to Falk for distribution in Europe.

21. In 2005, Paramount, Ovamed and the University negotiated a deal in which the University would license to Ovamed, and Ovamed simultaneously would sublicense to an affiliate of Paramount, all rights to clinically develop and commercialize TSO worldwide, with the exception of those limited rights already granted to BioCure in Europe.

22. On or about September 16, 2005, Ovamed's Chief Executive Officer, Detlev Goj, traveled to New York City to negotiate the basic terms of the contemplated sublicense from Ovamed to Collingwood. At that time, Paramount and Ovamed executed a non-binding Term Sheet that set forth the basic terms of the deal, which were to be incorporated in a definitive sublicense agreement. Goj signed the Term Sheet, which contained a New York choice-of-law clause, in New York City on Ovamed's behalf. (A copy of the Term Sheet is attached hereto as Exhibit B.)

23. The non-binding Term Sheet provided that Paramount would create and fund a new affiliated entity — ultimately, Collingwood — to engage in research, development and commercialization of TSO. Ovamed would grant to the new entity an exclusive sublicense to the patents, in exchange for payment of royalties based on a percentage of net sales of the product derived therefrom, and other payments that would be due upon the occurrence of various developmental milestones. The Term Sheet did not reserve to Ovamed any authority over the developmental program for TSO; paragraph 6 provided only that Collingwood would use "reasonable commercial efforts" to bring TSO to market "as timely and efficiently as possible."

24. Following the execution of the Term Sheet, Ovamed requested that Paramount negotiate on Ovamed's behalf an agreement with the University granting Ovamed an exclusive

license to the TSO patent rights, with the exception of certain uses in Europe that were the subject of BioCure's earlier agreement with Dr. Falk (the "License Agreement", a copy of which is attached hereto as Exhibit C). Members of Paramount's legal department, based in New York City, negotiated the terms of the License Agreement with the University.

25. Simultaneously, Paramount and Ovamed prepared the definitive Exclusive Sublicense Agreement contemplated by the Term Sheet. (A copy of the Exclusive Sublicense Agreement is attached hereto as Exhibit A.)

26. On or about December 12, 2005, Ovamed's Goj met with representatives of Paramount and Collingwood in New York City. At that meeting, Goj was provided final versions of the License Agreement negotiated between the University and Ovamed, as well as the Sublicense Agreement between Ovamed and Collingwood. Following the meeting, Goj executed both agreements in New York.

The Sublicense Agreement's Terms

27. The Sublicense Agreement granted Collingwood an exclusive sublicense to all of the TSO patent rights that were conveyed by the University to Ovamed under the License Agreement. *See* License Agreement §§ 1.1, 1.5, & 2.1; Sublicense §§ 1.2, 1.7, & 2.1.

28. Collingwood thus acquired the exclusive rights to develop and commercialize TSO in the covered territories. As contemplated by the Term Sheet, the Sublicense did not reserve to Ovamed any control over Collingwood's development of the TSO technology that Collingwood paid to license. Very much to the contrary, by alienating to Collingwood the exclusive rights to develop TSO, the Sublicense vested in Collingwood the sole discretion to determine the appropriate path for commercial development of the rights, subject only to Section

3.1's requirements that Collingwood's efforts be "commercially reasonable." *See* Sublicense § 3.1. To date, this work has been diligently performed on Collingwood's behalf by a TSO Development Team from Paramount.

29. The Sublicense Agreement contains a German choice-of-law clause in Section 18.1, but allows disputes thereunder to be resolved in any court having jurisdiction over the parties.

30. Under Section 262 of the German Civil Code, even where a contract does not specify which party is entitled to make a decision concerning the method of performance, the obligor is assumed to have the "election right," *i.e.*, the right to choose the appropriate method of performance.

31. As consideration for the sublicense of the patent rights, Ovamed is entitled to receive the payments set forth in Article 4 of the Sublicense Agreement, including an up-front licensing fee, royalties equal to 4% of net sales by Collingwood, and reimbursement for certain patent costs. Ovamed is also entitled to receive "Milestone Payments" upon the occurrence of certain events in the development and commercialization process. The first of these payments, in the amount of $1,500,000, is payable when Collingwood decides, in the exercise of its reasonable business judgment, that it is appropriate to file an investigational new drug application with the FDA, and the FDA accepts the IND. *See id.* § 4.3.1.

32. Consistent with Collingwood's control over the TSO development program, the Sublicense does not impose fixed dates by which Collingwood must achieve any of the events giving rise to Milestone Payments. Instead, it reflects a basic bargain in which Collingwood is charged with conceiving and executing a plan for development of TSO in the exercise of its

good-faith business judgment, and Ovamed is entitled to payments when in the course of that plan certain milestones are achieved.

33. The Sublicense also provided that Ovamed and Collingwood would negotiate in good faith a separate Manufacturing and Supply Agreement ("MSA"), under which Ovamed, upon request from Collingwood, would supply TSO "in amounts sufficient to satisfy [Collingwood's] clinical and commercial requirements." *Id.* § 3.2.

34. Following the execution of the Sublicense Agreement, Collingwood and Ovamed negotiated the terms of the MSA. On or about March 29, 2006, Collingwood forwarded an executed copy of the MSA reflecting the agreed terms to Ovamed. (A copy of the MSA is attached hereto as Exhibit D.)

The Pre-IND Meeting

35. Before any new drug can be introduced into interstate commerce in the United States, an investigational new drug application covering the drug must be approved by the FDA. *See generally* 21 U.S.C. § 355 & 21 C.F.R. Part 312. Thus, as a practical matter, an IND generally is a prerequisite to using a new drug in human clinical studies.

36. On December 13, 2005 — the day after the execution of the Sublicense Agreement —a pre-IND teleconference was convened with the FDA, during which meeting Paramount sought guidance regarding the development of TSO in a manner that would garner IND approval. Goj was present in Paramount's New York office during, and listened in on, the teleconference.

37. During the pre-IND teleconference, the FDA took the view that the existing toxicological data for TSO was not sufficient to demonstrate safety in humans. Accordingly, the

FDA advised Paramount, both during the meeting and in a subsequent confirming communication, to proceed with a planned 13-week toxicology study in Cynomolgus monkeys prior to submission of an IND application.

The Toxicology Study And The Need For GMP Product

38. Under FDA regulations, any drug used in human clinical trials must be produced in accordance with standards collectively referred to as current good manufacturing practice ("GMP" or "CGMP"). *See generally* 21 C.F.R. Parts 210-211. GMP consists of guidelines for appropriate controls, tests, and validations to be used in the manufacturing process to ensure that the product will be safe for human use.

39. The regulatory requirement to use GMP-grade product does not extend to toxicology studies per se. As explained below, however, Collingwood considered it commercially unwise and unduly risky to perform a live-monkey study for a "biologic" such as TSO using product manufactured according to a different (and non-GMP) process than would be used in clinical trials.

40. Broadly speaking, the FDA regulates two kinds of products: drugs and biologics. Drugs are relatively simple chemically-synthesized molecules. Biologics are generally derived from living material such as cells or whole microorganisms, and are therefore more structurally complex. TSO, which consists of the ova of the parasitic organism *Tricuris suis*, is a biologic.

41. Biologics traditionally have been treated separately from drugs because of their molecular complexity and difficulty to manufacture. A typical small-molecule drug, such as aspirin, has a readily-identifiable molecular structure. Imperfections in the manufactured product therefore can be identified readily via a chemical assay. By contrast, the methods for

identifying the clinically active components of a biologic product are more limited, and therefore such products typically are defined in important part by their manufacturing process. Indeed, the conventional view of biologics is that "the process is the product" — *i.e.*, a change in the manufacturing process, equipment, or facilities may result in significant changes to the product itself, such that it cannot be considered the same as one manufactured according to a different process. For this reason, changes in the manufacturing process of a biological product may result in the need for additional studies to establish the product's safety. *See, e.g.*, U.S. Food & Drug Administration, *Frequently Asked Questions About Therapeutic Biological Products* (2006), *available at* http://www.fda.gov/cder/biologics/qa.htm.

42. There is no way to know whether Ovamed's interim, non-GMP manufacturing process will be representative of the final process used to produce the GMP material required for human studies. As a result, while the primary purpose of the toxicology study was to demonstrate the product's safety for human trial, the use in the toxicology study of product manufactured according to Ovamed's existing non-GMP process would present a material risk that the FDA would consider the resulting data non-predictive of the toxicity risk presented by the GMP product to be used in human trials. Collingwood therefore determined that GMP product was needed for the toxicology study.

43. While the Sublicense Agreement vested Collingwood alone with discretion to assess the agent's most reasonable development pathway, discussions with the FDA added further support to Collingwood's considered judgment that GMP product should be used in the TSO toxicology study: Following the pre-IND meeting, Paramount sent the FDA a draft protocol for the toxicology study. In a follow-up conversation with Paramount's Vice President for Regulatory Affairs, a representative of the FDA confirmed that the product used in the

toxicology study should be similar in production to the product that would be used in the clinical study. Ideally, the FDA advised, the product used in the toxicology study and the subsequent clinical trials should come from the same manufacturing lot.

44. The FDA's recommendation that the product used in the toxicology study should be similar in production to, and ideally should come from the same manufacturing lot as, the product used in clinical trials — which must be produced according to GMP — reinforced Collingwood's view that GMP product should be used in the toxicology study, as well.

Collingwood's Quest For GMP Product And Ovamed's Inability To Provide It

45. In the months following the FDA's comments on the toxicology study protocol, Collingwood worked with two toxicology consultants to finalize the draft protocol. It also selected a laboratory in Germany to perform the study.

46. On July 11, 2006, the head of the TSO Development Team, Kim Weinberger, sent Ovamed a purchase order by electronic mail detailing Collingwood's need for TSO for the IND-enabling toxicology study. In her email, Dr. Weinberger explained that the toxicology study would be ready to commence on September 1, and that Collingwood required GMP material by that date. The MSA, executed by Collingwood and delivered to Ovamed in March 2006, expressly required Ovamed to deliver TSO "manufactured in compliance with CGMP and all other applicable regulatory and governmental regulations." *See* MSA § 5.1.

47. Contrary to the terms of the MSA, Ovamed was, and to this day remains, unable to supply GMP-grade material.

48. As a result of Ovamed's failure to provide GMP product, the toxicology study cannot be performed in the manner the TSO Development Team deems appropriate, and the IND cannot be filed.

49. Faced with a delay in the IND filing — and thus the related Milestone Payment — attributable to Ovamed's own inability to produce GMP product as called for under the MSA, Ovamed responded by arguing with the Development Team's judgment that GMP material should be used in the toxicology study. This insistence that the toxicology study be performed in a manner that the Development Team considers risky and imprudent, in order to accelerate the IND filing and trigger a milestone payment, is the basis of the parties' dispute.

50. In light of Ovamed's inability to provide GMP product, the TSO Development Team has diligently investigated potential alternative sources of GMP-grade TSO, so that it can commence the toxicology study without further delay. Following an extensive literature review, the Development Team identified a potential vendor, with whom it held detailed discussions regarding TSO production and bioanalytical development. Representatives from the Development Team made two visits to the vendor for further discussions and to tour the manufacturing facilities. Negotiations of the terms of a research and development agreement with the vendor are in process. The Development Team has invested literally scores of hours to identify and validate an alternative supplier of GMP-grade TSO.

51. While Collingwood's efforts to procure GMP-grade product would enable it to commence a toxicology study and proceed to an IND, Ovamed has sought to prevent Collingwood from procuring GMP-grade product elsewhere. Indeed, after Goj learned of Collingwood's efforts, he asserted in an email dated September 1, 2006 that any efforts to obtain TSO from another source constituted a violation of the MSA — the same MSA that required

Ovamed to supply Collingwood with GMP product. (A copy of the email is attached hereto as Exhibit E.)

52. In a letter dated October 11, 2006, Collingwood's German counsel responded to Ovamed, explaining that the MSA contained no exclusivity provision, and, in fact, expressly contemplated that Collingwood might seek other sources of TSO. (A copy of the letter is attached hereto as Exhibit F.)

Ovamed's Effort to Renegotiate the Parties' Agreements

53. Faced with the realization that the parties' agreements did not give it control over either the clinical development plan for TSO or the supply chain, Ovamed embarked on a campaign to renegotiate the terms of the parties' deal.

54. Having asserted in September that it was the exclusive provider of TSO under the MSA, Ovamed abruptly reversed course in a letter dated November 21, 2006, arguing that the MSA agreement was never executed by Ovamed, and that its terms were still subject to negotiation. (A certified English translation of the letter, as well as a copy of the German original, are attached hereto as Exhibit G.) Implicit in Ovamed's position was a refusal to supply TSO, even were Ovamed to have the capability to manufacture it on a GMP basis, until Collingwood agreed to an exclusivity provision that Ovamed had not bargained for in the existing agreement.

55. By letter dated January 2, 2007, Ovamed then extended its renegotiation efforts to the Sublicense Agreement. Acknowledging that the Sublicense Agreement as executed by the parties left the timing of the various development milestones to Collingwood's discretion, Ovamed's letter demanded that the agreement be altered to "set specific time limits" for the

Milestone Payments — which would effectively sever any connection between the payments and the actual achievement of developmental milestones. Most immediately, Ovamed demanded that Collingwood commence the monkey study despite the lack of GMP product, and "accelerate the IND," which would trigger a $1.5 million milestone payment to Ovamed. (A copy of the letter is attached hereto as Exhibit H.)

56. Collingwood responded on February 6, 2007, making clear its refusal to modify the freely-negotiated, binding terms of the Sublicense Agreement or the MSA. (A copy of the letter is attached hereto as Exhibit I.)

Ovamed's Claim of Breach and Threat to Terminate the Sublicense

57. Also on February 6, Ovamed's counsel sent a letter to German counsel for Collingwood and Paramount. Ovamed's letter asserted that Collingwood was in breach of Section 3.1 of the Sublicense Agreement because it had not proceeded with the toxicology study, or filed the IND application. Ovamed asserted that the delay had jeopardized funding for certain planned clinical studies, and caused Ovamed damages totaling several million euros. (A certified English translation of the letter, as well as a copy of the German original, are attached hereto as Exhibit J.)

58. Ovamed's letter also purported to set a deadline of May 13, 2007 for Collingwood to file the IND application.

59. Finally, the letter threatened termination of the Sublicense by invoking the Sublicense's termination provision, Article 9.1, as authority for the May 13 deadline.

Collingwood's Assignment to Sunset Cliffs

60. The Sublicense gives Collingwood the authority to assign its rights and duties thereunder, without Ovamed's consent, to an Affiliate. *See* Sublicense § 10.1.

61. Plaintiff Sunset Cliffs is an Affiliate of Collingwood, as that term is defined in section 1.1 of the Sublicense Agreement.

62. On April 27, 2007, Collingwood assigned its rights and duties under the Sublicense to Sunset Cliffs. (A copy of the assignment is attached hereto as Exhibit K.)

COUNT I
DECLARATORY JUDGMENT

63. Sunset Cliffs repeats and realleges the allegations in paragraphs 1 through 62 above as if fully set forth herein.

64. An actual controversy exists as to the rights and obligations of Sunset Cliffs under the Sublicense Agreement:

i. Contrary to the plain language of the Sublicense Agreement, and well-established principles of German contract law, Ovamed claims that Sunset Cliffs' predecessor-in-interest, Collingwood, breached Section 3.1 of the Sublicense Agreement by failing to file an IND application, and has threatened to terminate the Sublicense. Ovamed ignores the fact that Collingwood had, and Sunset Cliffs now has, a commercially reasonable basis for delaying the filing until after GMP-grade product can be procured for an IND-enabling toxicology study. Neither Sunset Cliffs nor Collingwood has breached the Sublicense.

ii. Ovamed also purports to set an arbitrary date, May 13, 2007, for the filing of an IND application with the FDA. Both the Sublicense Agreement and German contract law give Sunset Cliffs alone discretion to determine, in the exercise of its reasonable business judgment, when and how to take those steps. Sunset Cliffs is not obligated to file the IND, or achieve any other milestone in its exploitation of the rights that it paid to license, by any predetermined date.

iii. Finally, Ovamed has threatened to terminate the Sublicense Agreement by virtue of Collingwood's and Sunset Cliffs' refusal to accede to Ovamed's demands regarding the clinical and commercial development program for TSO, including how to conduct developmental trials, and when and under what circumstances to seek certain regulatory approvals. Ovamed's threat calls into question Sunset Cliffs' program for TSO development, and undermines Sunset Cliffs' ability to exploit the TSO rights as it sees fit in the exercise of its good-faith judgment. Aside from the threat's *in terrorem* effect, Sunset Cliffs' ability reliably to move forward with its development program is impaired so long as there is uncertainty regarding the extent, if any, of Ovamed's authority over it. Sunset Cliffs therefore requires a judicial construction of its contractual rights to control the program and timeline for development and commercialization of the TSO rights.

65. By reason of the foregoing, Sunset Cliffs is entitled pursuant to 28 U.S.C. § 2201(a) to a declaration that: (i) Sunset Cliffs and its predecessor-in-interest, Collingwood, have not breached the Sublicense Agreement; (ii) Sunset Cliffs is not obligated under the Sublicense Agreement to achieve any milestone in the development and commercialization of the sublicensed rights by a predetermined date certain; and (iii) under the Sublicense Agreement,

Ovamed has no authority to decide the appropriate program and timeline for development and commercialization of the sublicensed rights.

PRAYER FOR RELIEF

WHEREFORE, plaintiff Sunset Cliffs respectfully requests that the Court enter judgment declaring that:

(i) Sunset Cliffs and its predecessor-in-interest, Collingwood, have not breached the Sublicense Agreement;

(ii) Sunset Cliffs is not obligated under the Sublicense Agreement to achieve any milestone in the development and commercialization of the sublicensed rights by a predetermined date certain; and

(iii) Under the Sublicense Agreement, Ovamed has no authority to decide the appropriate program and timeline for development and commercialization of the sublicensed rights.

Dated: New York, New York
May 11, 2007

COVINGTON & BURLING LLP

By: _____
Jonathan M. Sperling (JS 0548)
Bradley J. Nash (BN 8002)

1330 Avenue of the Americas
New York, New York 10019
Telephone: (212) 841-1000

Attorneys for Plaintiff Sunset Cliffs Therapeutics, Inc.